

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
BENJAMIN A. RANDALL
238 10th STREET
TOLEDO, OH 43624

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of Mailing
(day/month/year)

17 DEC 2004

Applicant's or agent's file reference

TBA-02-04

REPLY DUE

within 2 months/days from
the above date of mailing

International application No.

PCT/US02/18976

International filing date (day/month/year)

14 June 2002 (14.06.2002)

Priority date (day/month/year)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61F 5/44 and US Cl.: 604/346

Applicant

ME & MY KIDZ, LLC.

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☒ Certain defects in the international application
 - VIII ☒ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 14 October 2004 (14.10.2004)

Name and mailing address of the IPEA/US

Mail Stop PCT, Attn: IPEA/ US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Karin M. Reichle

Telephone No. (571)272-3700

Sheila H. Venzky
Patent Specialist
Tech. Center 3700

Form PCT/IPEA/408 (cover sheet)(July 1998)

Best Available Copy

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I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☒ the description:
 pages 1-7, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☒ the claims:
 pages 8 and 9, as originally filed
 pages NONE, as amended (together with any statement) under Article 19
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☒ the drawings:
 pages 1-3, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☐ the sequence listing part of the description:
 pages NONE, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>3, 5 and 18</u>	YES
	Claims <u>1-2, 4, 6-17 and 19-20</u>	NO
Inventive Step (IS)	Claims <u>5 and 18</u>	YES
	Claims <u>1-4, 6-17 and 19-20</u>	NO
Industrial Applicability (IA)	Claims <u>1-20</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-2, 4, 6-17 and 19-20 lack novelty under PCT Article 33(2) as being anticipated by WITTES et al '548.

See abstract, Figures, col. 1, lines 16-19, col. 2, lines 5-7, 31-33 and 38-45, col. 3, lines 9-11, 47-52 and 61-64, col. 4, lines 1-3, 38-43, 48-51 and 63-64, col. 5, lines 26-28 and note that "membrane" as best understood is defined as a thin sheet of material" and "thin" is considered relative, "contiguous" is defined as "nearby, neighboring, adjacent" and "laminated" is defined as "to make by uniting thin layers", i.e. the WITTES et al device is considered to have an interior "membrane" laminated to an outer frame to form a structure with a single contiguous edge. The outer layer or shield is 10 and the inner layer is 36.

Claim 3 lacks an inventive step under PCT Article 33(3) as being obvious over WITTES et al '548.

Claim 3 requires a depth in the range of 0.5 to 2.5 inches whereas WITTES discloses a depth of approximately 0.37 inches. It is noted that the depth is disclosed as approximately 0.5 inches and the criticality of such depth has not been set forth. The WITTES reference discloses a curved re-useable shield shaped to a portion of the breast for minimizing visibility thereof through garments just like the disclosed invention and also discloses, e.g., at col. 4, lines 23-26, that other dimensions can be used. Therefore, since the general conditions of the claim are disclosed by Wittes, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Claims 5 and 18 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the inner layer being a gel of silicone rubber or a method for preventing let down of lactating fluid consisting of the claimed steps.

Claims 1-20 meet the criteria set out in PCT Article 33(4), and thus claims 1-20 have industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----

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VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

The drawings are objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or content thereof: In Figures 1-4, the line from 10 should be an arrow. This also applies to the line from 40 in Figures 4 and 6.

The description is objected to as containing the following defect(s) under PCT Rule 66.2(a)(iii) in the form or contents thereof: The Summary of the Invention section, i.e. a description of the claimed invention, and the invention of the claims should be commensurate in scope. Also on page 5, line 21 "Silicone" should be --silicone--. The sentence on page 6, line 22 does not make sense, i.e. "vice"? Antecedent basis for the method of claim 18 should be set forth. On page 2, line 6 the patent number is wrong. In claims 1-10, it is required that the laminate structure have a single "contiguous" edge. "Contiguous" as defined by the dictionary is "nearby; neighboring; adjacent", i.e. is used to describe something relative to another thing. Therefore, it is queried whether "contiguous" is the right descriptive term.

Claims 1-10, and 12-19 are objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: In claim 1, "the nipple" should be --a nipple-- and "the aureola" should be --an aureola--. In claims 2-10 and 12-17, line 1, "device" should be --shield--. In claim 19, line 2, "an" should be --the--.

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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claim 20 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim 20 is indefinite for the following reason(s): In claim 20, a positive antecedent basis for "an outer surface of said outer frame" should be established.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.